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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,005	08/01/2006	Philippe Perovitch	0540-1062	1374

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YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,005	PEROVITCH ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/01/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 3 and 5-12 were amended. New claims 13-20 were added.

2. Claims 1-20 are being presented for examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/01/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 9 and 10 recite the limitation of "metolose". The instant specification recites the use of "metolose" (Page 9) without describing what "metolose" actually is.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 1-3 and 13 recite the limitation "derivative of the aryl-carboxylic family". The term "derivative" is indefinite as it is unclear as encompassed by the term, and given the form of any number of compounds given an infinite number of chemical reactions, the compounds can be anything. Thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention.

11. Claims 9 and 10 contain the trademark/trade name METOLOSE®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hypromellose or hydroxypropyl methylcellulose and, accordingly, the identification/description is indefinite.

12. Claims 11 and 12 provide for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-8 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Finidori (US 6,056,944).

The claimed invention is a composition of lipophilic molecules that can be diffused in aqueous medium. The composition comprises at least one derivative of the aryl-carboxylic family and/or a lipophilic anti-inflammatory and/or a lipophilic anti-mycotic and/or a lipophilic analgesic of the morphine type and/or a lipophilic anti-allergic, in the form of salts of these molecules.

Finidori teaches a pharmaceutical composition for oral use comprising a nonsteroidal anti-inflammatory agent that includes ketoprofen lysine (Col. 1, lines 7-10 and Col. 2, lines 1-5). The composition can include carboxyvinyl polymers, polyethylene glycols, hydroxyethylcellulose, carboxymethylcellulose (CMC), alginates and sorbitol (Col. 2, lines 6-20). Xanthan gum is also disclosed as a component of the composition (Col. 4, line 20).

Regarding instant claims 1-8 and 13-20, the limitations of a "derivative" of the aryl-carboxylic family, a substrate that makes slow diffusion possible in the buccopharyngeal cavity, the amino acid (lysine), the polymer agents, and the substrates are anticipated by the teaching of a composition for oral use comprising ketoprofen lysine and including carboxyvinyl polymers, polyethylene glycols, hydroxyethylcellulose, carboxymethylcellulose, alginates, sorbitol and xanthan gum, as taught by Finidori (Col. 1, lines 7-10, Col. 2, lines 1-20, and Col. 4, line 20).

Regarding instant claims 11-12, the limitations of the use of the composition for treating buccopharyngeal ailments by diffusion are anticipated by the composition that

conveys an active agent into a target cell and that is useful for the treatment of periodontal disorders (Abstract and Col. 1, lines 22-27).

Therefore, the limitations of claims 1-8 and 11-20 are anticipated by the teachings of Finidori.

15. Claims 1-8 and 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pankhania et al. (WO 02/083119 A1).

Pankhania teaches a pharmaceutical composition comprising ibuprofen and includes the lysine salt of ibuprofen (Page 1, lines 3-6 and lines 13-14). The compositions are in a form suitable for oral administration (Page 4, lines 24-25). Suitable ingredients (including diluents, lubricating agents, disintegrating agents, binders and flow agents) for the composition include lactose, sucrose, magnesium stearate, alginic acid, croscarmellose sodium, carboxymethyl cellulose, polyvinylpyrrolidone, gelatin, hydroxypropylmethyl cellulose, and talc (Page 5, lines 21-34). Xanthan gum is disclosed as a release retarding agent (Page 6, lines 9-13). Diluents including sorbitol, xylitol, sucrose, flavorings, taste-masking agents, and aspartame are disclosed (Page 7, lines 10-17). Examples 18-23 disclose ibuprofen lysinate, lactose, croscarmellose sodium (sodium carboxymethylcellulose), magnesium stearate and polyvinylpyrrolidone (Page 21, lines 1-25).

Regarding instant claims 1-8 and 13-20, the limitations of a "derivative" of the aryl-carboxylic family, a substrate that makes slow diffusion possible in the buccopharyngeal cavity, the amino acid (lysine), the polymer agents, and the substrates

are anticipated by the teaching of a composition for oral administration comprising ibuprofen lysinate, lactose, sucrose, magnesium stearate, alginic acid, croscarmellose sodium, carboxymethyl cellulose, polyvinylpyrrolidone, gelatin, hydroxypropylmethyl cellulose, talc, xanthan gum, sorbitol, xylitol, sucrose, flavorings, taste-masking agents, and aspartame, as disclosed by Pankhania (Page 5, lines 21-34, Page 6, lines 9-13, and Page 7, lines 10-17).

Regarding instant claims 11-12, the limitations of the use of the composition for treating buccopharyngeal ailments by diffusion are anticipated by the controlled release composition where the active is incorporated into a matrix containing a release retarding agent (Page 5, lines 9-11 and Page 6, lines 9-13).

Therefore, the limitations of claims 1-8 and 11-20 are anticipated by the teachings of Finidori.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pankhania et al. (WO 02/083119 A1) in view of Mitra (WO 95/07103).

The teaching of Pankhania is stated above.

Pankhania does not expressly teach 25mg of ibuprofen lysinate.

Mitra teaches a pharmaceutical composition comprising from 5 to 50 mg S(+)-ketoprofen lysinate and a pharmaceutical composition comprising from 50 to 800 mg S(+)-ibuprofen lysinate (Page 13, claims 5-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising ibuprofen lysinate and the polymers and substrates, as taught by Pankhania, use the dosage of 50 to 800 mg ibuprofen lysinate, as suggested by Mitra, and produce the instant invention.

One of ordinary skill in the art would do this because the range of ibuprofen lysinate dosage is known in the art, as evidenced by the teaching of Mitra. One of ordinary skill in the art would have a reasonable expectation of success in producing a functional pharmaceutical product with a 50 to 800mg dosage of ibuprofen lysinate.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 9, the limitation of 25mg of ibuprofen lysinate would have been obvious over the dosage of 50 to 800 mg ibuprofen lysinate, as suggested by Mitra (Page 13, claim 6). The limitation of magnesium stearate, talc, aspartame, "metolose", arome, and sorbitol would have been obvious over the magnesium stearate, talc, aspartame, hydroxypropylmethyl cellulose, flavorings and sorbitol as taught by Pankhania (Page 5, lines 21-34, Page 6, lines 9-13 (Page 7, lines 10-17). The recited

dosages of the excipients would have been obvious over examples 18-23 disclosed by Pankhania (Page 21, lines 1-25). These are modifiable parameters that one of ordinary skill in the art can vary during the process of routine experimentation. The recited dosages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claim 10, the limitation of 5mg of ketoprofen lysinate would have been obvious over the dosage of 5 to 50 mg ketoprofen lysinate, as suggested by Mitra (Page 13, claim 5). The limitation of magnesium stearate, talc, aspartame, "metolose", arome, and sorbitol would have been obvious over the magnesium stearate, talc, aspartame, hydroxypropylmethyl cellulose, flavorings and sorbitol as taught by Pankhania (Page 5, lines 21-34, Page 6, lines 9-13 (Page 7, lines 10-17). The recited dosages of the excipients would have been obvious over examples 18-23 disclosed by Pankhania (Page 21, lines 1-25). These are modifiable parameters that one of ordinary skill in the art can vary during the process of routine experimentation. The recited dosages are obvious variants unless there is evidence of criticality or unexpected results.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615